UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,188	04/25/2001	John Warmington	054270-0134	3652

7590 12/26/2002

Stephen A. Bent
FOLEY & LARDNER
Washington Harbour
3000 K Street, N.W., Suite 500
Washington, DC 20007-5109

EXAMINER	
SHAHNAN SHAH, KHATOL S	

ART UNIT	PAPER NUMBER
1645	10

DATE MAILED: 12/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/841,188	WARMINGTON ET AL.	
	Examiner	Art Unit	
	Khatol S Shahnan-Shah	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *9-12 and 16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,13-15 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-17* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 April 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicants' amendment of January 24, 2002, paper No. 4 is acknowledged. Claims 4, 6, and 7 were amended. New claim 17 was added.

Election/Restrictions

2. Applicants' election with out traverse of September 25, 2002 in Paper No. 9 is acknowledged.

Applicants elected Group I claims (1-8, 13-15 and 17) directed to a method of diagnosing *Candida albicans* infection.

3. Currently claims 1-17 are pending. Claims 9-12 and 16 are withdrawn from consideration as being drawn to non elected inventions.

4. Claims 1-8, 13-15 and 17 are under consideration.

Abstract

5. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Drawings

6. The drawings are approved by the Draftsperson.

Specification

7. The disclosure is objected to because of the following informalities:

Specification page 10, lines 15-20 some kind of special brackets have been used. Use of these special brackets is not appropriate.

Appropriate correction is required.

8. The use of the trademark such as API has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Applicants' cooperation is requested to review the entire specification for all possible minor errors and correct any errors of which applicant may become aware of in the specification.

Claim Objections

9. Claim 8 is objected to because of the following informalities:

Claim 8 recites the phrase " wherein the biological sample is sera".

Sera is plural form of serum. Since biological sample is singular, it will be more appropriate to use the word serum in place of sera. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

10. Claims 1-8, 13 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are:

The claim is drawn to a method of diagnosing infection however, essential method steps are not clear for example, it is not clear how the antibody levels were measured or when the antigen was added to the sample?

It is not clear what applicants intend in reciting the phrase " immunodominant antigen (enolase)" in claim 13. Are there any other immunodominant antigens involved or enolase is the only immunodominant antigen?

Claims 6, 7 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for reciting improper Markush group. Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being " selected from the group comprising of A, B, and/or C." See exparte Markush, 1925 C.d. 126 (Comm'r Pat. 1925).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-8 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Buckley et al. (US 4,806,465).

The claims are drawn to a method of diagnosing *Candida* infection, comprising the steps of:

a) obtaining a biological sample from a subject;

b) measuring antibodies to *Candida* cytoplasmic antigens.

Buckley et al. discloses a method of diagnosing *Candida* infection, comprising the steps of:

a) obtaining a biological sample from a subject;

b) measuring antibodies to *Candida* cytoplasmic antigens.

See claims specially claims 1-4.

Buckley et al. teach ELISA, RIA, latex agglutination, immunoblot assay and other suitable antigen detection systems (see columns 2 and 17).

Since the office does not have the facilities for examining and comparing applicants' method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i. e., that the method of prior art does not possess the same material structure and functional characteristics of the claimed method). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Buckley et al. (US 4,806,465) in view of Ballantyne et al. (Biotechnology and Applied Biochemistry, Vol.31, pp. 213-218, 2000).

The claim is drawn to a method of diagnosing *Candida* infection, comprising the steps of:

a) obtaining a biological sample from a subject;

b) measuring antibodies to *Candida* cytoplasmic antigens in combination with measuring antibodies to enolase.

Buckley et al. discloses a method of diagnosing *Candida* infection, comprising the steps of:

a) obtaining a biological sample from a subject;

b) measuring antibodies to *Candida* cytoplasmic antigens.

See claims specially claims 1-4.

Buckley et al. teach ELISA, RIA, latex agglutination, immunoblot assay and other suitable antigen detection systems (see columns 2 and 17). Buckley et al. teach only cytoplasmic antigen and do not teach other antigens such as enolase. Ballantyne et al. teach purification of enolase from medically important candida species and their importance in developing serological assays using the enolase antigen (see abstract and page 217).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to further include the purified enlose taught by Ballantyne et al in the methods of diagnosis taught by Buckley et al. to obtain the instant invention.

One of ordinary skill in the art would have been motivated to do this by the teaching of Ballantyne et al. about the importance of developing serological assays using the enolase antigen (see page 217) to develop a method of diagnosis using more than one antigen for detecting *Candida* infection.

14. Claims 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buckley et al. (US 4,806,465) in view of Miyada et al. (US 5,766,874).

The claims are drawn to a kit for diagnosing *Candida* infection, comprising:

a) obtaining a biological collecting device;

b) a *Candida* cytoplasmic antigen; and

c) means for detecting reaction between the antibody and antigen in the sample.

Buckley et al. discloses a method of diagnosing *Candida* infection, comprising the steps of:

a) obtaining a biological sample from a subject;

b) measuring antibodies to *Candida* cytoplasmic antigens.

See claims specially claims 1-4.

Buckley et al. teach ELISA, RIA, latex agglutination, immunoblot assay and other suitable antigen detection systems (see columns 2 and 17). Buckley et al. teach do not teach diagnostic kit. However use of kits in immunodiagnosis are well known in the art for example Miyada et al. teach kits for diagnosis of *Candida* infections (see claims).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to arrange the reagents and material used in the methods of diagnosis taught by Buckley et al. in form of a kit to obtain the instant invention.

One of ordinary skill in the art would have been motivated by the teaching of Miyada al. to do this in order to obtain a method and a kit to simplify and optimize diagnostic techniques to detect candida infections or disease.

Conclusion

14. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnan-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached on Monday through Friday from 7:30 AM - 4 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned to is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

Art Unit 1645

December 19, 2002

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER